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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,480	03/31/2004	Karen K.Y. Young	022101-000230US	8589

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EXAMINER

SALVOZA, M FRANCO G

ART UNIT	PAPER NUMBER
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1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/815,480

Applicant(s)

YOUNG, KAREN K.Y.

Examiner

M. Franco Salvoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-33 and 40-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-33 and 40-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim 28 has been amended.

Claims 28-33, 40-50 are under consideration.

Election/Restrictions

Applicant contends that the restriction does not conform to the governing law and recites case law such as *In Re Weber, Soder and Boksay*; there is no statutory basis for rejecting a claim for misjoinder; the added costs of filing and prosecuting additional patent applications does not strike an appropriate balance between the administrative concerns of the Office and applicant's statutory and constitutional rights; claims 28-50 would never be considered on the merits and render the applicant incapable of capturing the scope of the invention; there is no legitimate basis for restriction between independent and dependent claims; the restriction requirement is per se improper and should be withdrawn.

Applicant's arguments are considered but found unpersuasive. Restriction is proper as deemed by MPEP § 803, reciting that the claims of an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP §802.01 §806.06 and § 808.01) or distinct (MPEP §806.05 – §806.05(j)).

In this case, the original claims recited a variety of sequences (SEQ ID NO: 8, SEQ ID NO:9, SEQ ID NO: 16, SEQ ID NO:15, SEQ ID NO: 74, SEQ ID NO:28) which in and of themselves are deemed to be independent and distinct inventions for reciting structurally distinct products. However, in light of the invention reciting a kit employing specific SEQ ID NO:s

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specifically for detecting and amplifying nucleic acid sequences, improved detection and amplification by use of additional sequences, Group IV was restricted and designated for election and comprises three sequences, a reasonable number of species in light of MPEP § 803.04 as well as the invention recited in specification.

The Office regrets any additional costs that may incur, however the restriction is necessary for a proper and thorough examination of the claims.

The restriction is maintained for reasons of record.

Claim Rejections - 35 USC § 103

MAINTAINED

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28, 40, 41, and 48-50 were rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al. in view of Beasley and Lanciotti with Buck et al. cited in support.

Claims 29-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al. in view of Beasley and Lanciotti with Buck et al. cited in support. in view of Will et al.

Claims 42 and 47 were rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al. in view of Beasley and Lanciotti with Buck et al. cited in support. in view of Rigler et al.

Claim 44 was rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al. in view of Beasley and Lanciotti with Buck et al. cited in support. in view of Lanciotti et al.

Applicant contends that none of the cited art alone or in combination teaches or suggests all the limitations recited in claim 28 as clarified by amendment; the references accession numbers merely relate to long genomic sequences that include one or more of the claimed oligonucleotides; the oligonucleotides recited in amended claim 28 include nucleotide sequences that are conserved between different strains and are at most 100 nucleotides in length; the art fails to teach the utility of the conserved regions, rather just disclose large genomic sequences; the Action has not established a prima facie case of obviousness with respect to claim 28 or suggestion or motivation to modify the cited art or to combine the teachings to achieve the claimed invention.

Applicants arguments are considered but found unpersuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the position of the Office will be further clarified in light of the existing rejection as well as applicant's amendment to claim 28.

Erlich et al. teaches a kit for detection and amplification of nucleic acids from viruses (Erlich et al. more specifically teaches as preferred embodiments shorter nucleotide lengths as primers, depending on a variety of factors such as effectiveness of hybridization: "The exact lengths of the primers will depend on many factors, including temperature and source of primer

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and use of the method. For example, depending on the complexity of the target sequence, the oligonucleotide primer typically contains 15-25 or more nucleotides, although it may contain more or fewer nucleotides” (column 6 line 41)); Beasley et al. teaches a sequence comprising SEQ NO: 8 for flavivirus West Nile, a member of the Japanese virus serogroup; Lanciotti et al. teaches genomic West Nile virus (again a member of the Japanese encephalitis serogroup) corresponding to SEQ ID NO:s 9 and 16. In light of the teachings of *In Re Deuel* and *In re Fout* as recited in the previous Office Action, the primers and probes are prima facie obvious for representing structural homologs of the genomic flavivirus nucleotides, and further, an express suggestion to substitute equivalent components is not necessary to render the substitution obvious, and even further, Buck et al. teaches the equivalence of primers.

While applicant has amended claim 28 to merely recite specific shorter lengths of nucleotides, in light of the teachings of Buck et al. and Erlich et al., it would have been obvious to one of ordinary skill in the art that any shorter sequence derived from said SEQ ID NO:s would be effective as a primer and for detection and amplification. Additionally, one of ordinary skill in the art would have been additionally motivated to use conserved regions of specific viruses in order to improve detection of one specific virus or group of viruses (such as flavivirus or JEV) over others.

Applicant has merely presented arguments but has not pointed to any unexpected results or specific secondary considerations that would particularly point to particular regions of the cited sequences that would render the rejection unobvious, as the claims were only amended to recite claim lengths, which, as indicated by supporting reference of Buck et al. as well as the

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teachings of *In Re Deuel* and *In re Fout* would indicate a reasonable expectation of success for any primer or shorter nucleotide sequence derived from said recited SEQ ID NO:s.

The rejection is maintained for reasons of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


M. Franeo Salyoza
Patent Examiner



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